



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/565,068

07/13/2006

Parry John Guilford

PEBL-01006US1

3673

66936 7590 09/28/2010

BORSON LAW GROUP, PC
1078 CAROL LANE, #200
LAFAYETTE, CA 94549

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

09/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,068	Applicant(s) GUILFORD ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 3-6,13-18 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-12,19-21,25,26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/17/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on September 17, 2010 has been entered.

2. Claims 1-6, 9-26 and 28-30 are pending.

Claims 3-6, 13-18 and 22-24, drawn to non-elected inventions are withdrawn from examination.

Claims 8 and 27 have been cancelled.

Claims 1, 2, 9-12, 19-21, 25 and 28-30 have been amended.

Claims 1, 2, 9-12, 19-21, 25, 26 and 28-30 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. Applicants' information disclosure statement (IDS) submitted September 17, 2010 was reviewed and considered, however Applicants are reminded that all corresponding information including publication dates should accompany the citation. In this instant case the Examiner has provided the missing information. Nevertheless, Applicant is advised in the future the absence of this information the IDS may fail to meet the provisions of 37 CFR 1.97, 1.98 and MPEP § 609, see MPEP § 609.05(a).

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 1, 2, 9-12, 19-21, 25, 26 and 28-30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendment to claims 1, 19 and 20 submitted September 17, 2010. Claims 8 and 27 have been cancelled.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The rejection of claims 1, 2, 9-12, 19-21, 25, 26 and 30 under 35 U.S.C. 102(e) as being anticipated by Afar et al./ U.S. Patent Application Publication number US 2003/0232350 A1 (filed November 13, 2002) is maintained. Claims 8 and 27 have been cancelled.

Applicants assert Afar does not disclose, nor enable detecting CST1 protein in a blood sample, see Remarks submitted September 17, 2010, page 6. Applicants conclude arguments noting amendments made to the claims render the instant rejection moot. These points of view and arguments have been carefully considered, but found unpersuasive.

As cited in the Final Rejection mailed March 18, 2010 on page 5 and reiterated herein, the publication discloses a method of immunodiagnosing

Art Unit: 1643

stomach cancer comprising identifying and comparing diagnostic markers listed in Table 2A including *cystatin SN (SEQ ID NO: 108)*, see page 36, line 60; page 88, line 33; the sequence alignment following the instant rejection; page 10, section 0067; and page 19, section 0158. The diagnostic markers are detected in biological samples include *blood*, plasma, serum and stool, see page 14, section 0096. Diagnostic assays implemented include standard immunoassays, such as ELISAs using antibodies capable of detecting polypeptides and peptides, see page 19, sections 0157, 0158; page 20, section 0161; and page 22, section 0175. A number of markers are evaluated for differential expression between normal and cancerous tissues, see page 10, section 0067-page 11, section 0071. Examples of additional diagnostic markers to be assessed are kallikrein 10 (KLK10), page 36, line 71; matrix metallopeptidase 12 (MMP12), page 38, line 28; and phospholipase A2, page 88, line 3. Consequently, the rejection is maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The rejection of claims 1, 2, 9-12, 19-21, 25, 26 and 28-30 under 35 U.S.C. 103(a) as being unpatentable over Afar et al./ U.S. Patent Application Publication number US 003/0232350 A1 (filed November 13, 2002), and further in view of Mack et al./ U.S. Patent Application Publication number US 2004/0076955 A1 (filed July 2, 2002) and Clarke et al./ U.S. Patent Application Publication number US 2006/0019256 A1 (effective filing date June 9, 2003) is maintained. Claims 8 and 27 have been cancelled.

Applicants assert amendments made to the claims render the instant rejection moot, see Remarks, page 7. This point of view has been carefully considered, but found unpersuasive.

The primary reference, Afar does not fall based on the teachings set forth in the preceding 102(e) rejection. Particularly, Afar teaches a method of immunodiagnosing stomach cancer comprising identifying and comparing diagnostic markers, including *cystatin SN (SEQ ID NO: 108)* and a host of others in biological samples including *blood*, see page 14, section 0096; page 36, line 60; page 88, line 33; the sequence alignment following the instant

Art Unit: 1643

rejection; page 10, section 0067; and page 19, section 0158. The diagnostic markers are detected in biological samples include **blood**, plasma, serum and stool, see page 14, section 0096. Afar does not teach measuring overexpression of the multitude of markers set forth in dependent claims 2, 21 and 28-30.

However, Mack teaches a method of diagnosing several solid cancers comprising identifying and comparing diagnostic markers listed in Tables 1A-13 including cystatin SN in many types of samples using diagnostic assays, see page 2, sections 0026-0030; page 3, section 0054; page 11, section 0108; page 21, section 0209; page 108, Table 4a; and page 112, Table 6A, Pkey number 409757. Examples of additional diagnostic markers to be assessed are olfactomedin, (OLFM1), page 35; SPARC-like 1, page 36; matrix metalloproteinase 12 (MMP12), inhibin (INHBA), pages 45, 55 and 58; lysyl oxidase, page 54; lumican (LUM), page 126; thrombospondin 2 (THBS2), page 134; TGFB inducible early growth response (page 9A); kallikrein 11 (page 150); aldican (page 154); and chondroitin sulfate proteoglycan 2 (page 167).

Moreover, Clark teaches characterizing and diagnosing cancer by assessing several markers, serine or cysteine proteinase inhibitor clade B (SERPINB5), secreted acidic cysteine-rich protein (SPARC) see page 12, lines 2 and the 25th line from the bottom of the page and serine or cysteine proteinase inhibitor clade H (SERPINH1), see page 13, line 16. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was

Art Unit: 1643

made to include these cancer markers designated in Mack and Clarke for gastric cancer diagnosis. One of ordinary skill in the art would have been motivated to use these particular markers because the secondary references teach these markers' upregulated expression is consistent with solid tumors, such as gastrointestinal cancer, see Clarke page 5, section 0050.

Consequently, the rejection is maintained.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a ***flexible schedule***, however she can normally be reached between the hours of 7:30 am to 6:30 pm, Monday-Saturday, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Misook Yu, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
21 September 2010

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643

Application/Control Number: 10/565,068
Art Unit: 1643

Page 10